



## **Pixium Vision announces positive preclinical safety and feasibility data for PRIMA, a tiny, wireless subretinal implant**

### **Retinal safety of near infrared radiation in photovoltaic restoration of sight**

*H. Lorach, J. Wang, Y. Lee, R. Dalal, P. Huie and D. Palanker*

### **Validation of photovoltaic subretinal implants on ex-vivo blind non-human primate retinas**

*PH. Prevot, S. Picaud*

**Paris, 07 January 2016** – Pixium Vision (FR0011950641 - PIX), a company developing innovative bionic vision systems to allow patients who have lost their sight to lead more independent lives, announced that new positive preclinical thermal safety and feasibility data for PRIMA, its second generation Vision Restoration System (VRS), were published and presented.

For **Khalid Ishaque, CEO of Pixium Vision**, *“Our prestigious academic partners have, once more, provided important preclinical data demonstrating development progress of PRIMA, our second generation system. The team at Stanford University has published positive thermal safety of PRIMA in chronic use and in parallel, the Vision Institute in Paris tested the PRIMA chip in a primate retina, the most realistic model of degenerate human retina.”* **Khalid Ishaque** added: *“We are confident that PRIMA continues to demonstrate a very positive safety profile. Pixium Vision and its partners will continue to generate further safety data to meet the company’s goal of a first PRIMA human implant in 2016.”*

The study led by H. Lorach and Professor D. Palanker, from the Department of Ophthalmology and Hansen Experimental Physics Laboratory at Stanford University, demonstrated thermal safety of near infrared stimulation of PRIMA in a well-established animal model for retinal damage assessment in laser treatment. The selected model provides conservative estimation compared to human eye. In typical use conditions of the PRIMA implant (5mW/mm<sup>2</sup>, 5ms pulses at 20-40Hz), the estimated temperature increase ranges from 0.17°C to 0.43°C. The system meets the required standards as the temperature increase is more than 4 times below the recommended thermal safety limit of 2°C for active implanted medical devices in chronic use at a power level that allow in-vivo stimulation with the PRIMA implant.

In parallel, PH. Prevot and S. Picaud, from the Vision Institute in Paris (Institut de la Vision), demonstrated that PRIMA electrically activated the ganglion cell layers (surface of the retina where the optic nerve starts) well within the optical safety limits in a primate retina where photoreceptors had been previously removed. The team could determine, in a realistic model of the degenerate retina, activation thresholds that are well within the optical safety limits, and demonstrate consistent, reproducible, spatially localized responses to projected patterns.

#### ***Find the publication on:***

<https://www.osapublishing.org/boe/abstract.cfm?uri=boe-7-1-13&origin=search>

#### ***Find the scientific programme on:***

<http://www.artificial-vision.org/#scientific-programme>

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## About Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com))

Pixium Vision's VRS are associated with a surgical intervention as well as a rehabilitation period.

Clinical trials are currently underway with the VRS IRIS® in several centers in Europe. Patients have tolerated their implants well so far and improvements in visual perception have been observed. Pixium Vision has filed IRIS's CE mark dossier at the end of 2015 and expects CE mark approval by mid-2016.

Pixium Vision is also developing PRIMA, a sub retinal implant currently in preclinical trial. The Company plans to begin clinical trials of PRIMA in Europe in 2016.

The company is EN ISO 13485 certified.

Pixium Vision works in close collaboration with world famous academic partners such as the Vision Institute in Paris and the Hansen Experimental Physics Laboratory at Stanford University.



Pixium Vision is listed on Euronext (Compartiment C) in Paris.

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## About light intensity standards

The light intensity is limited by both the ocular laser safety standards (ISO 60825 and ISO 15004) and the thermal safety standards for active implantable medical devices (AIMD) (ISO 14708-1:2014 / EN 45502-1:1997). The first one defines the maximum permissible power that can enter the eye for a specific wavelength, beam size and exposure duration, whereas the second one defines a maximum temperature on the surface of an implant.

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